

REMARKS/ARGUMENTS

Applicant has received and carefully reviewed the Office Action mailed November 2, 2009. Currently, claims 1-14, 16-29, and 31-41 are pending, with claims 11, 12, and 14 previously withdrawn from consideration. Claims 1-10, 13, 16-29, and 31-41 have been rejected. Applicant respectfully traverses all adverse assertions and rejections presented in the Office Action. Favorable consideration of the following remarks is respectfully requested.

Claim Rejections – 35 USC § 103

Claims 1-10, 13, 16-21, 23-29, and 31-41 were rejected under 35 U.S.C. §103(a) as being unpatentable over Huebsch et al. (U.S. Patent No. 6,312,446) in view of Hart (U.S. Patent No. 5,846,251) and Lafontaine et al. (U.S. Patent No. 5,964,782). After careful review, Applicant must respectfully traverse the rejection.

“All words in a claim must be considered in judging the patentability of that claim against the prior art.” *In re Wilson*, 424 F.2d 1382, 1385, 165 USPQ 494, 496 (CCPA 1970). If an independent claim is nonobvious under 35 U.S.C. 103, then any claim depending therefrom is nonobvious. *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988). (MPEP 2143.03).

The Office Action acknowledges that Huebsch et al. do not disclose the collapse actuator assuming a deformed profile solely in response to a sufficient proximal force applied to the collapse actuator in order to permit the detachable distal end to pass proximally through the distal aperture, as required by independent claims 1, 26, and 33. Instead, Huebsch et al. appear to teach actuator 230 may be detached from closure device 200 by rotating distal end 232 of actuator 230 to align with distal opening 234 in closure device 200 and then pulling the actuator proximally through the device. Huebsch et al. do not appear to teach or suggest deforming the actuator to facilitate removal.

The Office Action has proposed to modify distal end 232 of actuator 230 of Huebsch et al. based upon the teachings of Hart to provide a deformable distal end to facilitate retraction and removal of the actuator without the need for its rotation to ensure passage through the distal aperture. Applicant believes that the proposed modification is improper.

“If proposed modification would render the prior art invention being modified unsatisfactory for its intended purpose, then there is no suggestion or motivation to make the proposed modification. *In re Gordon*, 733 F.2d 900, 221 USPQ 1125 (Fed. Cir. 1984)...If the proposed modification or combination of the prior art would change the principle of operation of the prior art invention being modified, then the teachings of the references are not sufficient to render the claims *prima facie* obvious. *In re Ratti*, 270 F.2d 810, 123 USPQ 349 (CCPA 1959)”. (MPEP 2143.01 V-VI).

Applicant submits that modification of actuator end 232 of Huebsch et al. to permit it to deform such that the deformed end may be pulled through opening 234 without rotation, as proposed in the Office Action, may render the device unsuitable for its intended use and thereby impermissibly alter the principle of operation of Huebsch et al. Applicant submits that in order to perform the required proximal collapse of closure device 200, a certain amount of force must be applied. In order to deform end 232 after collapse of the device, additional force will be required. One of ordinary skill in the art will surely recognize that excessive force applied to an apparatus being used to plug a tissue opening may have detrimental effects, and thus would not be compelled to make the proposed modification. Applicant submits that the additional force required to facilitate the asserted deformation may render the device unsuitable for its intended use, as it will subject the affected tissue to additional pulling forces and stresses, which could promote undesirable bleeding, tissue damage, or pull-through of the closure device. Similarly, the device of Huebsch et al. appears to be based upon the principle of a rigid actuator 230 applying a needed force to closure device 200 followed by rotation of the actuator to facilitate removal of the actuator without applying additional unneeded force or stress to the treated tissue opening. Nowhere do Huebsch et al. appear to consider that actuator 230 may be pulled through distal opening 234 without rotation. Accordingly, the proposed modification of Huebsch et al. in view of Hart appears to be improper, and thus incapable of supporting the asserted obviousness rejection.

Additionally, the Office Action also acknowledges that Huebsch et al. do not disclose “the collapsible backing being made of pile or fabric, wherein the pile tissue engaging hooks engage portions of the pile backing to retain the pile backing in the collapsed position”.

Lafontaine et al. is introduced in an effort to supply “a bioabsorbable pile backing 344 with tissue or adventitia engaging hooks that entangle in the backing located proximal of the hooks as the backing moves from the non-collapsed position to the collapsed position to retain the backing in a collapsed configuration”, citing Figs. 34A-34C.

Applicant submits that even if the device of Huebsch et al. is modified as proposed in the Office Action, the claimed closure device is not obtained. Therefore, inclusion of the pile backing of Lafontaine et al. does not appear to remedy the shortcomings of Huebsch et al.

While the Office Action has not made it clear exactly how the device of Huebsch et al. is to be modified to include the pile backing of Lafontaine et al., for the sake of discussion Applicant assumes that the pile backing is to be added to the exterior surface of device 200. If the exterior of the struts of Huebsch et al. is covered with the backing of Lafontaine et al., the hooks thereon would not appear to engage with the backing when the struts are in their collapsed configuration.

Each half of closure device 200 appears to have struts that bend at hinge points 225, such that the struts of each half also each have a proximal and distal portion. The proximal portions of the distal struts (struts distal of central portion 218) and the distal portions of the proximal struts (struts proximal of central portion 218) each appear to face the tissue of an area having a defect after installation. The distal portions of the distal struts and the proximal portions of the proximal struts each appear to face away from the tissue defect being treated.

Hooks disposed along the proximal portions of the distal struts and along the distal portions of the proximal struts would appear to be prevented from contacting the pile of the opposing strut because they are separated by the intervening tissue and are also spaced apart by the central portion (218) of the device.

Similarly, hooks disposed on the proximal portion of the proximal struts and the distal portion of the distal struts appear to face away from any other portion of the device that may have the proposed pile, and thus the hooks cannot engage the pile.

In the Response to Arguments, the Office Action states that “the hooks of the proximal portion would engage the pile of the proximal portion and the hooks of the

distal portion would engage the pile of the distal portion, therefore maintaining the collapsed configuration". Applicant respectfully disagrees, initially noting that the proposed addition of the pile of Lafontaine et al. to the closure device of Huebsch et al., for the purpose of maintaining the device in the collapsed configuration, appears to be unnecessary in view of the locking elements already in place on closure device 200.

It is unclear to the Applicant how "the hooks of the proximal portion would engage the pile of the proximal portion and the hooks of the distal portion would engage the pile of the distal portion". As modified, pile on the exterior surface of Huesbch et al. does not appear to collapse onto itself in any way that will facilitate the asserted engagement. If it is being suggested to replace the struts of Huebsch et al. with the pile of Lafontaine et al., rather than adding the pile to the struts, Applicant submits that such a modification significantly alters the principle of operation of Huebsch et al., and thus is impermissible.

Furthermore, it is unclear to the Applicant how engaging the hooks of the proximal portion with the pile of the proximal portion and the hooks of the distal portion with the pile of the distal portion will maintain the device in the collapsed configuration, as asserted in the Office Action. Engaging the hooks to the pile on the same portion of the device, to the extent such a configuration is even possible, would appear to have no effect on maintaining the device in the collapsed configuration.

If, for the sake of argument, the Office Action is instead proposing to add the pile backing of Lafontaine et al. to the interior surface of the closure device of Huebsch et al., Applicant respectfully submits that such a modification does not satisfy the limitations of the claims. Applicant respectfully points out that the independent claims 1 and 33 recite "tissue engaging members" disposed on the backing, and independent claim 26 recites both "pile engaging hooks and tissue engaging hooks" disposed on the backing. Applying the backing of Lafontaine et al. to the interior surface of closure device 200 does not appear to provide tissue engaging members disposed on the backing, as it appears that only the exterior surface of device 200 contacts and engages the surrounding tissue.

Therefore, the proposed combination of Huebsch et al. and Lafontaine et al. does not appear to achieve the configuration required by the claims.

For at least the reasons discussed above, Huebsch et al. in view of Hart and Lafontaine et al. do not appear to properly combine to teach or suggest all of the claim limitations of independent claims 1, 26, and 33, as is required to establish a *prima facie* case of obviousness. Therefore Applicant believes claims 1, 26 and 33 are indeed patentable over the cited references. Since claims 2-10, 13, 16-21, 23-25, 27-29, 31, 32, and 34-41 depend from claims 1, 26, or 33 and add additional elements thereto, Applicant believes that these claims are also patentable over the cited references. Applicant respectfully requests that the rejection be withdrawn.

Claim 22 was rejected under 35 U.S.C. §103(a) as being unpatentable over Huebsch et al. (U.S. Patent No. 6,312,446) in view of Hart (U.S. Patent No. 5,846,251) and Lafontaine et al. (U.S. Patent No. 5,964,782), as applied to claim 21, and further in view of Luscombe et al. (U.S. Patent No. 5,683,418). After careful review, Applicant must respectfully traverse the rejection.

If an independent claim is nonobvious under 35 U.S.C. 103, then any claim depending therefrom is nonobvious. *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988). (MPEP 2143.03).

Additionally, and similar to the discussion above, modification of actuator 230 of Huebsch et al. with a feature that requires additional proximal force to be applied appears to impermissibly alter the principle of operation of the device, rendering it unsuitable for its intended use. One skilled in the art will recognize the potential dangers associated with applying additional pulling forces to device 200 during a treatment procedure and thus would not be compelled to modify the device in the way proposed.

For at least the reasons discussed above, independent claim 1 is believed to be patentable. Since claim 22 depends therefrom and adds additional elements thereto, claim 22 is also believed to be patentable. Withdrawal of the rejection is respectfully requested.

Conclusion

In view of the foregoing, all pending claims are believed to be in condition for allowance. Further examination, reconsideration, and withdrawal of the rejections are

respectfully requested. Issuance of a Notice of Allowance in due course is anticipated. If a telephone conference might be of assistance, please contact the undersigned attorney at (612) 677-9050.

Respectfully submitted,

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By his Attorney,



Date: Jan. 21, 2010

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